* * * * *

Dated: November 24, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–29476 Filed 12–04–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 182 and 186

[Docket No. 80N–0196]

Japan Wax; Affirmation of GRAS Status as an Indirect Human Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm Japan wax as generally recognized as safe (GRAS) as an indirect food ingredient for use as a constituent of cotton and cotton fabrics used in dry food packaging. The safety of this indirect food use of Japan wax has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 5, 1995.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

In the Federal Register of June 1, 1995 (60 FR 28555), FDA published a proposal to affirm the GRAS status of the use of Japan wax as an indirect human food ingredient migrating to food from cotton and cotton fabrics used in dry food packaging. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on Japan wax, as well as documents in the possession of FDA and further evidence of the safety of Japan wax obtained by FDA since publication of the Select Committee's report, have been made available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

The proposal gave interested parties an opportunity to submit comments. FDA received no comments on its proposal. The agency is, therefore, adopting the proposal without any changes.

Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule that published in the Federal Register of June 1, 1995 (60 FR 28555). No new information or comments have been received that would affect the agency's determination that there is no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses.

The agency finds that this rule is not a significant regulatory action as defined by Executive Order 12866. Furthermore, in accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses, and determined that this rule will have no significant adverse impact on a substantial number of small businesses. FDA has received no new information or comments that would alter its previous determination.

Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective December 5, 1995 (5 U.S.C. 553(d)(1)).

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 186

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 182 and 186 are amended to read as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§ 182.70 [Amended]

2. Section 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* is amended by removing the entry for ''Japan wax.''

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 186 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. New § 186.1555 is added to subpart B to read as follows:

§ 186.1555 Japan wax.

(a) Japan wax (CAS Reg. No. 8001–39–6), also known as Japan tallow or sumac wax, is a pale yellow vegetable tallow, containing glycerides of the C_{19}–C_{23} dibasic acids and a high content of tripalmitin. It is prepared from the mesocarp by hot pressing of immature fruits of the oriental sumac, *Rhus succedanea* (Japan, Taiwan, and Indo-China), *R. vernicifera* (Japan), and *R. trichocarpa* (China, Indo-China, India, and Japan). Japan wax is soluble in hot alcohol, benzene, and naphtha, and insoluble in water and in cold alcohol.

(b) In accordance with paragraph (b)(1) of this section, the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based on the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: November 24, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–29478 Filed 12–04–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 53 and 301

[TD 8628]

RIN 1545–A077

Political Expenditures by Section 501(c)(3) Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding excise taxes, accelerated tax assessments, and injunctions imposed for certain political expenditures made by organizations that (without regard to any political expenditure) would be described in section 501(c)(3) and exempt from taxation under section 501(a). These regulations reflect changes to the law that were enacted as part of the Revenue Act of 1987.

EFFECTIVE DATE: These regulations are effective December 5, 1995.

FOR FURTHER INFORMATION CONTACT: Cynthia Morton or Paul Accettura, (202) 622–6070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 14, 1994, proposed regulations §§ 53.4955–1, 301.6852–1, and 301.7409–1 under sections 4955, 6852 and 7409 were published in the Federal Register (59 FR 64359). In addition, amendments were made to regulations under other sections in order to reflect the effects of sections 4955, 6852, and 7409. Proposed regulation amendments in §§ 1.6091–2, 53.4963–1, 53.6011–1, 53.6071- 1, 53.6091–1, 301.6211–1, 301.6212–1, 301.6213–1, 301.6861–1, 301.6863–1, 301.6863–2, 301.7422–1, and 301.7611–1 were also published in the Federal Register (59 FR 64359). No public hearing was requested or held. The IRS received two comments on the proposed regulations, only one of which offered substantive suggestions. The IRS and the Treasury Department have considered the public comments on the proposed regulations, and the regulations are adopted as revised by this Treasury decision.

Explanation of Provisions

The regulations provide guidance with respect to sections 4955, 6852 and 7409. The sanctions in these sections apply to all organizations described in section 501(c)(3). Before sections 4955, 6852 and 7409 were enacted in 1987, revocation of recognition of exemption was the sole sanction available against political intervention by public charities. Section 4955 was modeled on the section 4945 excise tax on political expenditures (taxable expenditures) by private foundations, while sections 6852 and 7409 provide new sanctions against flagrant political expenditures and flagrant political intervention, respectively.

One comment on the proposed regulations requested that the regulations define in additional detail the term *political expenditure* and provide specific examples of activities that constitute intervention or participation in a political campaign for or against a candidate. Section 53.4955–1(c)(1) of the proposed regulations provides that any expenditure that would cause an organization that makes the expenditure to be classified as an action organization in accordance with § 1.501(c)(3)–1(c)(3)(iii) is a political expenditure within the meaning of section 4955(d)(1). By referring to the long standing action organization regulations, § 53.4955–1(c)(1) of the proposed regulations ties the definition of *political expenditure* in section 4955 to existing IRS and judicial interpretations of when an organization participates or intervenes in a political campaign on behalf of or in opposition to any candidate for public office in violation of the requirements of section 501(c)(3). The IRS and the Treasury Department believe this direct connection between section 4955 and section 501(c)(3) correctly implements the intent of Congress as expressed in the statute and the legislative history. To the extent that further guidance is needed on the interpretation of the terms political expenditure under section 4955 and intervening in political campaigns under section 501(c)(3), the IRS and the Treasury Department believe such guidance should be given in connection with the requirements for tax exemption under section 501(c)(3). Therefore, the final regulations have not revised § 53.4955–1(c)(1).

Another comment suggested that the regulations specify whether there were circumstances under which conduct would result in the imposition of a tax under section 4955 but not in revocation of exemption under section 501(c)(3). According to the statutory language and the legislative history of section 4955, the addition of that section to the Internal Revenue Code did not affect the substantive standards for tax exemption under section 501(c)(3). To be exempt from income tax as an organization described in section 501(c)(3), an organization may not intervene in any political campaign on behalf of any candidate for public office. Consistent with this requirement, section 4955 does not permit a de minimis amount of political intervention. Therefore, the final regulations have not been revised. However, there may be individual cases where, based on the facts and circumstances such as the nature of the political intervention and the measures that have been taken by the organization to prevent a recurrence, the IRS may exercise its discretion to impose a tax under section 4955 but not to seek revocation of the organization's tax-exempt status.

One comment raised questions about the interpretation of section 4955(d)(2), which relates to organizations formed primarily to promote the candidacy of a particular individual. The comment requested clarification of the standard for determining whether an organization ''is formed primarily for purposes of promoting the candidacy (or prospective candidacy) of an individual for public office'' under section 4955(d)(2). The comment also requested clarification of the meaning of the phrase ''availed of'' in the section 4955(d)(2) reference to organizations availed of primarily to promote an individual's candidacy for public office. The comment further requested examples of expenses which have the primary effect of promoting public recognition or otherwise primarily accruing to the benefit of a candidate or a prospective candidate.

The legislative history of section 4955 provides that the determination of whether an organization's primary purpose is the promotion of the candidacy or prospective candidacy of an individual for public office is based on all relevant facts and circumstances. The proposed regulations follow the legislative history. The IRS and the Treasury Department believe that, if more detailed guidance is necessary, it would be more appropriate to provide it in a form that allows for the consideration of a fuller range of facts and circumstances. Therefore, the final regulations have not been revised.

The comment also asked whether section 4955(d)(2) adds anything to the